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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,881	09/29/2003	Hidenori Yamada	21581-00303-US	5366

30678 7590 05/22/2006

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EXAMINER
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LILLING, HERBERT J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/671,881

Applicant(s)

YAMADA ET AL.

Examiner

HERBERT J. LILLING

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 and 2 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 02-19-2004 (1 page) 02-01-1998
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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1. Receipt is acknowledged of the election response filed April 21, 2006.
2. Claims 1-4 are pending in this application.
3. Applicant has elected without traverse Group III, Claims 3-4, drawn to a method of introducing a protein or peptide into cells and election drawn to species (a) avidins which Claims 3 and 4 read on the elected species.
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3 and 4 are rejected under 35 U.S.C. 102(e) as anticipated by Schacht et al US 6,312,727 or Miller et al US 6,974,698:

The reference, Schacht et al US 6,312,727, teaches the following which is clearly within the scope of the claimed invention as anticipatory as recited:

1. A method of constructing a synthetic polymer-based carrier vehicle for delivery of nucleic acid material to target cells in biological systems, wherein said method comprises carrying out separately but sequentially the steps of:
  - (a) bringing the nucleic acid material into association with cationic polyelectrolyte polymer material to form by self-assembly there between a polyelectrolyte complex which provides a nucleic acid containing cationic polymer core for said carrier vehicle, and
  - (b) reacting said polyelectrolyte complex with reactive hydrophilic polymer

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material whereby the latter bonds to said complex and forms a hydrophilic coating that provides an outer protective steric shield and assists in stabilising the complex, so that a synthetic polymer-based carrier vehicle for delivery of nucleic acid material is formed, said hydrophilic polymer material being composed of a synthetic polymer backbone having side chains which terminate in reactive groups and which contain an oligopeptide spacer, said hydrophilic polymer material including between 4% and 10% of said oligopeptide spacer containing side chains, so that the synthetic polymer-based vehicle is constructed.

7. A method as claimed in claim 1 ... in which the cationic polyelectrolyte polymer material incorporates reactive binding groups selected from the group consisting of biotin, avidin and streptavidin.

Miller et al US 6,974 recites the following:

In preferred embodiments, the ligand is avidin or streptavidin. Avidin can be bound directly to the biologically active molecule, e.g. an enzyme, through the carbohydrate chains on the avidin molecule, thus leaving all biotin binding sites on avidin free to interact with the biotinylated cell surface. Alternatively, avidin can be conjugated to a cationic polymer, such as polyethylenimine, and the resulting avidin-cationic polymer conjugate is then complexed with the biologically active molecule, that is, a polyanion, such as a nucleic acid, an oligonucleotide or a protein, creating a "ligand conjugate-biologically active molecule" complex. In a specific embodiment, polyethylenimine (PEI) is the cationic polymer, and the PEI-avidin conjugates are herein referred to as "PA conjugates". Conjugates of PEI-avidin can be made with increasing amounts of avidin, depending on the particular application.

or, in the alternative, under 35 U.S.C. 103(a) as obvious over the references disclosure with any amendment to the claimed subject matter absent unexpected or any unobvious process steps clearly indicated in the next office or any declaration or evidence supporting any amendments to the claimed subject matter.

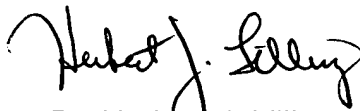
5. No claim is allowed.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918** and **Fax Number** is (703) 872-9306 or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.J.Lilling: HJL  
(571) 272-0918  
Art Unit **1651**  
May 09, 2006



Dr. Herbert J. Lilling  
Primary Examiner  
Group 1600 Art Unit 1651